UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF MICHIGAN SOUTHERN DIVISION

UNITED STATES OF AMERICA ex rel. RUSSELL E. DINGLE and THOMAS L. REMPFER,

Plaintiffs,

v. Case No. 5:00-CV-124

BIOPORT CORPORATION and ROBERT MYERS,

HON. GORDON J. QUIST

Defendants.

OPINION

Plaintiff/Relators' Complaint is a *qui tam* action filed pursuant to the False Claims Act, 31 U.S.C. §§ 3729-3733 ("FCA"). The Complaint contains allegations of irregularities regarding production of anthrax vaccine pursuant to certain government contracts and resulting false claims filed and paid. Defendants Bioport Corporation ("Bioport") and Robert C. Myers ("Myers") have jointly filed a motion to dismiss. For the reasons stated in this Opinion, the motion is denied.

FACTS

Plaintiff/Relators, Russell E. Dingle ("Dingle") and Thomas L. Rempfer ("Rempfer"), are members of the United States Air Force Reserve. (Compl. ¶¶ 8-9.) Formerly, both were members of the Air National Guard for Connecticut, and in that capacity they became familiar with the government's anthrax vaccine program. (Id.) Specifically, both Dingle and Rempfer were members

of a military research team investigating the anthrax vaccine and its safety for human use. (Compl. ¶¶ 8-9.)

Together, Dingle and Rempfer (hereinafter referred to as "Plaintiffs") filed this *qui tam* action, pro se, on behalf of the United States government and themselves.¹ Pursuant to the FCA, the Complaint was placed under seal to allow the government time to make a decision as to whether it would actively prosecute the case. On September 21, 2001, the government filed its Notice of Election to Decline Intervention. On September 25, 2001, the case was ordered unsealed so that it could proceed.

Defendants in this matter are Bioport and Myers, who is the Chief Executive Officer of Bioport. (Compl. ¶¶ 11-12.) Bioport came into existence as a corporation in May 1998, and Plaintiffs acknowledge in their Complaint that Bioport acquired the government contracts for anthrax vaccine in September of 1998 from the Michigan Biologic Products Institute ("MBPI"). (Compl. ¶ 11.) The parties agree that the MBPI was formerly known as the Biologic Products Division ("BPD") and that at some point in the past the BPD was a division within the State of Michigan's Department of Public Health. Myers was involved with the MBPI as well.

Defendants have moved to dismiss this case on several grounds. The Court's rulings follow:

A. Compliance with Fed. R. Civ. P. 4(m)

Defendants assert that service of process in this matter was not timely. On April 8, 2002, this Court entered an order that directed the Court Clerk to reissue the summons and also directed Plaintiffs to accomplish personal service upon Defendants within fifteen days of April 8. Defendants acknowledge, and the Proof of Service in the court file shows, that Defendants were served on April

¹Prior to oral argument on the pending motion, Plaintiffs engaged counsel.

11, 2002, just three days after the Order and well within the fifteen-day requirement. Thus, Defendants' arguments regarding dismissal of the action for failure to timely serve are moot, and this portion of Defendants' motion will be denied.

B. <u>Pleading of Subject Matter Jurisdiction</u>

Next, Defendants argue that Plaintiffs have failed to properly plead and/or invoke this Court's subject matter jurisdiction. They seek to dismiss the Complaint pursuant to Fed. R. Civ. P. 12(b)(1). This argument fails for the following reasons:

- 1. Pursuant to 28 U.S.C. § 1331, this Court has jurisdiction to hear actions based upon the FCA because such actions arise under the laws of the United States. In addition, § 3732 of the FCA vests jurisdiction in this Court. Therefore, this Court possesses subject matter jurisdiction for FCA cases such as this.
- 2. Defendants' argument that Plaintiffs failed to plead their "standing" by not specifically pleading § 3730(b)(1) of the FCA, thus stripping this Court of subject matter jurisdiction, fails. There is no provision in the FCA that requires Plaintiffs to specifically plead that subsection, and it appears that Defendants' argument is misplaced, being one of failure to state a claim, not of subject matter jurisdiction. In addition, Defendants cite no legal authority for their assertion. § 3730(b)(1) of the FCA merely states:

A person may bring a civil action for a violation of section 3729 for the person and for the United States Government. The action shall be brought in the name of the Government. The action may be dismissed only if the court and the Attorney General give written consent to the dismissal and their reasons for consenting.

Simply speaking, this subsection prescribes the form of the caption and rules for dismissal. In the present case, Plaintiffs allege their individual status, (Compl. ¶¶ 8-9), are "persons," and the government was named. Plaintiffs have standing to bring the action.²

3. Defendants' argument that § 3730(e)(4)(A) of the FCA is required to be pled to invoke subject matter jurisdiction is also misplaced. That subsection prohibits a *qui tam* action if the underlying facts have been publicly disclosed unless the plaintiff is the original source of the underlying facts. Herein, Defendants do not argue that there was such a public disclosure of the facts and/or that Plaintiffs are not original sources. If an action does not meet the standards set forth in § 3730(e)(4)(A), the Court has no jurisdiction, but Plaintiffs specifically cited § 3730 in Paragraph 13 of their Complaint to invoke this Court's jurisdiction. That cite was tantamount to asserting that the jurisdictional bar found in § 3730(e)(4)(A) did not apply.

C. Compliance with Fed. R. Civ. P. 9(b)

Plaintiffs' Complaint evidences detailed information regarding the history of the production of the anthrax vaccine and details regarding government contracts with Bioport's predecessor(s) for its production. Plaintiffs claim that the essence of their complaint is that every invoice or bill submitted by Bioport's predecessor(s) to the United States for payment was fraudulent in that it did not disclose the difference in manufacturing processes and/or equipment after the original process and equipment was certified by the United States. Plaintiffs claim that this information is sufficient to satisfy the requirements of Fed. R. Civ. P. 9(b), i.e., every claim presented by Bioport's predecessor(s) to the United States was false.

²See also <u>Vermont Agency of Natural Resources v. United States ex rel. Stevens</u>, 529 U.S. 765, 778, 120 S. Ct. 1858, 1865 (2000)("a *qui tam* relator under the FCA has Article III standing.")

The Court agrees with Plaintiffs that this is sufficient to meet the requirements of Fed. R. Civ. P. 9(b), subject to one problem. During oral argument, Defendants stated that the manufacturing changes complained of were in fact ratified by the government early on. Plaintiffs disagreed, and it is evident to the Court that the specific date(s) of the changes, as well as the date(s), if any, that the government had notice of said changes must be alleged with particularity. This is necessary not only for purposes of Rule 9(b), but also for the statute of limitations issue.

Therefore, Plaintiffs must amend the Complaint to notify Defendants precisely of the underlying acts supporting their claim of fraud – i.e., the dates equipment and/or processes were changed and the date or dates that the invoices therefore became fraudulent.

D. Statute of Limitations

Defendants argue that Plaintiffs are barred from raising any claims that arose prior to October 12, 1994. Defendants assert that a six year statute of limitations in the FCA applies and that six years runs backward from October 12, 2000, the filing date of the Complaint.³

The statute of limitations for actions brought pursuant to the FCA is found in § 3731(b):

A civil action under section 3730 may not be brought —

- (1) more than 6 years after the date on which the violation of section 3729 is committed, or
- (2) more than 3 years after the date when facts material to the right of action are known or reasonably should have been known by the official of the United States charged with responsibility to act in the circumstances, but in no event more than 10 years after the date on which the violation is committed,

whichever occurs last.

³The Court notes that the Complaint was filed under seal on October 10, 2000, not October 12 as asserted by Defendants. However, based upon the Court's holding in this Opinion regarding the statute of limitations, the 2-day difference is irrelevant.

Subsection (b) was added in 1986 and is commonly known as the "equitable tolling" provision.

Defendants assert that subsection (b) is not available to Plaintiffs since the government chose not to intervene in this matter. Defendants' argument fails for the following reasons:

- 1. Section 3731(b) expressly refers to "[a] civil action under section 3730." This reference is to § 3730 in *toto*, without any specific exclusions or restricted applications. Subsection (a) of § 3730 gives the Attorney General the right to bring a civil action for violations of § 3729. Subsection (b) of § 3730 extends this same right to a "person," known in the caption as a "relator." Nowhere does § 3731(b)(2) restrict its application solely to actions under § 3730(a).
- 2. Neither the United States Supreme Court nor the United States Court of Appeals for the Sixth Circuit has directly addressed this issue. However, in <u>Vermont Agency of Natural Resources v. United States ex rel. Stevens</u>, 529 U.S. 765, 774 n.4, 120 S. Ct. 1858, 1863 n.4 (2000), the Supreme Court stated that "we are asserting that a *qui tam* relator is, in effect, suing as a *partial* assignee of the United States." The issue in that case was whether a relator could bring suit in federal court under the FCA against a state or state agency, given the strictures of the Eleventh Amendment. However, the Court's recognition of a *qui tam* plaintiff as a partial assignee of the government, when applied to the present case, results in a finding that such a plaintiff would share in the government's ability to avail itself of the extended statute of limitations.
- 3. In <u>United States ex rel. Hyatt v. Northrop Corp.</u>, 91 F.3d 1211, 1213 (9th Cir. 1996), the court held:

No distinction is made between civil actions brought by the government under § 3730(a) and those brought by *qui tam* plaintiffs under § 3730(b). Indeed, there is nothing in the entire statute of limitations subsection which differentiates between private and government plaintiffs at all. If Congress had intended the tolling provisions of § 3731(b)(2) to apply solely to suits brought by the Attorney General, it could have easily expressed its specific intent.

The Court finds this language persuasive.

This does not mean that Plaintiffs are free of potential FCA statute of limitation problems when the law is applied to the facts in the present case; that issue is not before the Court at this time. Findings of fact made in regard to changes in processes or equipment, claims submission and payment, as well as the United States' knowledge of some or all of the changes in equipment and/or processes, could invalidate some or all claims. This ruling merely sets forth the law that will be applied to those facts.

E. Failure to State A Claim

In <u>United States ex rel. Compton v. Midwest Specialities, Inc.</u>, 142 F.3d 296 (6th Cir. 1998), the plaintiff alleged that defendant supplied the government with nonconforming goods. As stated in that case:

Midwest correctly argues that a mere breach of contract, without any evidence of scienter, is insufficient to establish liability under the False Claims Act. However, even pre-1986 precedent makes clear that a manufacturer who knowingly supplies nonconforming goods to the government, based on a belief that the nonconforming goods are just as good as the goods specified in the contract, is liable.

<u>Id.</u> at 304. Since this Court must accept Plaintiffs' allegations as true for purposes of the present motion, and since Plaintiffs have pled that the anthrax vaccine produced pursuant to the government contracts was nonconforming and that Defendants knew it was nonconforming, Plaintiffs have stated a claim.

In addition, since Defendants submitted their motion and brief to the Court, the Sixth Circuit has issued a decision on the false implied certification theory. That theory rests on the premise that government contractors have a continuing duty to comply with regulations underlying their contracts; each submission of a claim carries with it implicit verification that those regulations have been

adhered to. In <u>United States ex rel. Augustine v. Century Health Services, Inc.</u>, 289 F.3d 409 (6th Cir. 2002), the Sixth Circuit said:

Instead, [defendants'] appeal is premised on the notion that, in order for liability to attach under the FCA, a claim must be expressly false at the time it was submitted. We disagree. As noted above, a number of courts have held that a false implied certification may constitute a false or fraudulent claim even if the claim was not expressly false when it was filed. Instead, liability can attach if the claimant violates its continuing duty to comply with the regulations on which payment is conditioned. We adopt this theory of liability . . . [Also,] we agree with the Tenth Circuit's holding that, "when FCA liability is premised on an implied certification of compliance with a contract, the FCA nonetheless requires that the contractor knew, or regardlessly disregarded a risk, that its implied certification of compliance was false."

Id. at 415-16 (quoting Shaw v. AAA Eng'g & Drafting, Inc., 213 F.3d 519, 533 (10th Cir. 2000)). Paragraphs 25-37 of the Complaint sufficiently allege that Defendants failed to adhere to federal regulations in producing the anthrax vaccine and failed to notify the government of the same. As one example, in Paragraph 36 Plaintiffs allege that "Bioport redated expired vaccine without an approved stability testing procedure as required by 21 C.F.R. § 211.137."

The fact that Defendants argued against the imposition of the false certification theory in their response brief demonstrates that they are on notice of this theory early in the case. There is no requirement that the theory itself be pled; rather, just the facts to support the theory. 2 James W. Moore, Moore's Federal Practice, ¶ 8.04[3] (3d. ed. 1997). Therefore, Defendants' motion will be denied on this issue.

F. Conspiracy Counts IV and V

Defendants argue that Counts IV and V of the Complaint, which allege conspiracy, should be dismissed with prejudice pursuant to Rule 12(b)(6). Defendants' argument is premised on the assertion that no facts to support such conspiracy allegations have been pled, and in any event, the claims are barred as a matter of law.

The FCA, specifically § 3729(a)(3), imposes liability on "[a]ny person who . . . conspires to defraud the Government by getting a false or fraudulent claim allowed or paid." The Sixth Circuit's decision in <u>United States v. Murphy</u>, 937 F.2d 1032, 1034 (6th Cir. 1991), which addressed § 3729(a)(3), stated:

"A civil conspiracy is an agreement between two or more persons to injure another by unlawful action. Express agreement among all conspirators is not necessary to find the existence of a civil conspiracy. Each conspirator need not have known all of the details of the illegal plan or all of the participants involved. All that must be shown is that there was a single plan, that the alleged conspirator shared in the general conspiratorial objective, and that an overt act was committed in furtherance of the conspiracy that caused injury to the complainant."

The question of whether a person was a participant in a conspiracy is a question of fact.

⁴The Court notes that the time of accrual of a cause of action under the FCA is not before it.

G. Successor Liability

Defendant Bioport seeks dismissal of any and all claims that relate in time to MBPI or BPD. This argument has several bases: 1) no allegation in the Complaint that Bioport incurred successor liability from its predecessor(s); 2) the non-existence of successor liability pursuant to the terms of the Asset Purchase Agreement; and 3) Eleventh Amendment "derivative" sovereign immunity.

1. Pleading of Successor Liability

Plaintiffs alleged Bioport's purchase of MBPI in the Complaint and indicated that both entities would be referred to as "Bioport." Thus, the allegations in the Complaint relating to pre-September 1998 events use "Bioport" as the actor. However, by the very nature of combining the two entities, it is readily apparent that Plaintiffs allege that Bioport and MBPI are one and the same for purposes of the Complaint. While perhaps not artfully pled by these *pro se* litigants, it is reasonable to infer that Plaintiffs were asserting successor liability.

2. Transfer of Liabilities

There are many references in the Asset Purchase Agreement between the State of Michigan and Bioport as to which liabilities are assigned to Bioport and which liabilities are retained by the State. In addition, there is language in the Novation Agreement signed by those parties and the federal government (which assigns the MBPI/USA contracts to Bioport) regarding the transfer of liabilities.

Defendants rely on Section 1.3.2 of the Asset Purchase Agreement as evidence that Bioport did not assume the liabilities asserted by Plaintiffs:

1.3.2 <u>Retained Liabilities</u>. Purchaser shall not assume by virtue of this Agreement or the transactions contemplated hereby, and shall have no liability for, any other Liabilities incurred in, or which arise in connection with, the Operations of the Institute or the conditions of the Real Property Owned prior to the Closing Date (the "<u>Retained Liabilities</u>").

(Asset Purchase Agreement at 4, Pls.' Resp. Br. Ex. J.) If this were the only document executed by the parties in connection with the sale, Defendants might be correct. However, the Novation Agreement, which transferred the government contracts at issue from MBPI to Bioport, contains the following language:

(a) The Parties agree to the following facts:

. .

- (4) The Transferee has assumed all obligations and liabilities of the Transferor under the contracts by virtue of the above transfer.
- (b) In consideration of these facts, the parties agree that by this Agreement . . .
 - (2) The Transferee agrees to be bound by and to perform each contract in accordance with the conditions contained in the contracts. The Transferee also assumes all obligations and liabilities of, and all claims against, the Transferor under the contracts as if the Transferee were the original party to the contracts.
 - (3) The Transferee ratifies all previous actions taken by the Transferor with respect to the contracts, with the same force and effect as if the action had been taken by the Transferee.

. . .

(5) Except as expressly provided in this Agreement, nothing in it shall be construed as a waiver of any rights of any rights of the Government against the Transferor for any matters directly relating to the contracts which occurred prior to the date of this Novation Agreement.

(Novation Agreement at 1-2, Pls.' Resp. Ex. J.) Thus, while Bioport may not have assumed FCA liability pursuant to the Asset Purchase Agreement, the Court finds that it directly stepped into the shoes of the BPD and MBPI by executing the Novation Agreement, and successor liability attaches.⁵

⁵The two agreements are not inconsistent. There are many potential liabilities (e.g. environmental) for which the Asset Purchase Agreement provides Bioport with protection outside of the government contracts that were assigned.

3. **Sovereign Immunity**

Defendants argue that the BPD and MBPI were agencies of the State of Michigan, and thus,

Eleventh Amendment immunity applies. In other words, even if successor liability exists, the

predecessor to Bioport was the State of Michigan, which could not be sued by Plaintiffs.

If the Novation Agreement did not exist, Defendants' argument might be persuasive.

However, pursuant to the language of the Novation Agreement quoted above, Bioport assumed the

government contracts at issue in this matter "as if the Transferee were the original party to the

contracts" and Bioport "ratifie[d] all previous actions taken by the Transferor with respect to the

contracts, with the same force and effect as if the action had been taken by the Transferee." In

executing the Novation Agreement, Bioport affirmed and adopted the actions of the BPD and MBPI

as if it had performed the acts itself. Thus, Bioport cannot now rely on sovereign immunity to avoid

potential liability for those acts.

Conclusion

Defendants' motion to dismiss is denied for the reasons stated herein. However, Plaintiffs

must amend the Complaint as set forth in this Opinion to comply with Rule 9(b). An Order in accord

with this Opinion shall be entered.

Dated: August 29, 2002

/s/ Gordon J. Quist

GORDON J. OUIST

UNITED STATES DISTRICT JUDGE

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UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF MICHIGAN SOUTHERN DIVISION

UNITED STATES OF AMERICA ex rel. RUSSELL E. DINGLE and THOMAS L. REMPFER,

Plaintiffs,

v. Case No. 5:00-CV-124

BIOPORT CORPORATION and ROBERT MYERS,

HON. GORDON J. QUIST

Defendants.

ORDER

For the reasons stated in the Court's Opinion filed on this date,

IT IS HEREBY ORDERED that Defendants' motion to dismiss (docket no. 21) is **DENIED**.

IT IS FURTHER ORDERED that within twenty-one (21) days of the date of this Order, Plaintiffs shall file an amended complaint which sets forth in the detail required by Fed. R. Civ. P. 9(b) the following information:

- describe each change of process or equipment which underlies the false claims alleged in the Complaint;
- 2) for each change described in subparagraph number 1) set forth the date the change was made;

3) state whether Plaintiffs have knowledge of whether an official of the United

States charged to act in circumstances had knowledge of the change and, if

so, the date the official first obtained such knowledge.

Failure to file the amended complaint within the time ordered will cause this Court to reconsider the

Defendants' motion to dismiss for failure to plead fraud with particularity as required by Rule 9(b)

and will probably result in dismissal of the Complaint.

This Order is being entered, in part, to help the Court and parties focus upon the issues in this

case in order to achieve the purposes set forth in Fed. R. Civ. P. 1 and 16.

Dated: August 29, 2002

/s/ Gordon J. Quist

GORDON J. QUIST

UNITED STATES DISTRICT JUDGE